

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: 10/510,368 Confirmation No.: 8789  
Applicants: Lefere *et al.*  
Filed: October 19, 2004  
Art Unit: 3768  
Examiner: Katherine L. Fernandez  
Title: SYSTEM, FORMULATION, KIT AND METHOD FOR TAGGING COLONIC  
RESIDUE IN AN INDIVIDUAL

Docket No.: 048777/283575  
Customer No.: 00826

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION OF PRIOR INVENTION UNDER 37 C.F.R. § 1.131**

We, Philippe Lefere and Archie Williams, hereby declare and state that:

1. We are the inventors of the subject matter claimed in the above-identified U.S. Patent Application Serial No. 10/510,368, filed October 19, 2004, which is a U.S. National Stage application under 35 U.S.C. §371 of International Patent Application No. PCT/US2003/010588, filed April 5, 2003, which claims the benefit of U.S. Provisional Patent Application Serial No. 60/370,661, filed April 2, 2002. This Declaration is filed to establish conception and reduction to practice prior to February 21, 2002.


2. We are aware of the document Lauenstein et al., "MR Colonography with Barium-based Fecal Tagging: Initial Clinical Experience", *Radiology*, 223, (1): 248-254, which was cited by the United States Patent and Trademark Office in the Action dated October 16, 2008. It is our understanding that this document was first published on-line on February 21, 2002.

3. Prior to February 21, 2002, in the United States, we conceived and reduced to practice the present invention, which provides methods of preparing an individual for a predetermined activity that requires the tagging of at least some colonic residue in the individual's digestive tract.

4. In support of this statement, attached to the present declaration is the following exhibit, which is a true and accurate copy of an original document with the exception of the redaction therefrom of the date and of confidential information unrelated to the present application:

*Exhibit A* provides an internal, company memorandum prepared by the inventor Archie Williams providing a discussion of various aspects of the invention, particularly the incorporation of tagging agent in food items and administration over a time frame to provide a specific amount of tagging agent. In this exhibit, certain information has been redacted as it includes confidential information that is unrelated to conception or reduction to practice of the present invention. This memorandum was prepared prior to February 21, 2002.

5. We hereby declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

  
Philippe Lefcure

04/16/2007  
Date

  
Archie Williams

15 April 09  
Date

**EXHIBIT A**

To: [REDACTED]

Cc: [REDACTED]

Ref: Stool Tagging

Date: [REDACTED]

Most everyone knows the history of how we came to develop stool tagging contrast, so I will not bore you with those details. [REDACTED]

We started working on stool tagging and did a pretty good job demonstrating that barium will penetrate stool and given in sufficient volume it will homogeneously tag stool.

We then started combining tagging with nutritional support and laxation. The nutritional support became a major project. [REDACTED]

First, as we are doing, we should incorporate the tagging agent in the meal supplement.

Secondly, [REDACTED] increasing the number of doses we give the patients. [REDACTED]

Currently we are dosing the patients with one 250 ml of Banana Smoothie at 2% w/v or 5 grams of BaSO<sub>4</sub> per dose. We are giving the patients one with each meal or three doses totaling 750 ml @ 15 grams of BaSO<sub>4</sub>. [REDACTED]

[REDACTED] Remember the colon pulls fluid out of the contents in the bowel and causes the contrast in the colon to increase in concentration.

[REDACTED]

I would like to keep this to a one day protocol. To do this I recommend that we formulate the meal supplement to generate a 2% w/v concentration per meal and the total volume per meal should equal 500 ml.

This will yield a delivered dose per meal of 10 grams, twice the delivered dose per meal when compared to our current design. We administer three of the meals in one day for a total of 1500 ml @ 30 grams of BaSO<sub>4</sub>. We have doubled our delivered dose and kept the protocol to one day, the day before the exam.

We could add an additional meal/dose the morning of the exam to sustain the patient prior to the procedure and to tag any fluids and stool that may find its way to the cecum prior to the exam.

This would give us a potential delivered dose of 40 grams. [REDACTED]

[REDACTED]

[REDACTED] at some point you need to eliminate the contents that reside in the GI tract at the time you start the prep/tagging protocol. This could be a mild laxative to encourage colonic evacuation. While you may not be required to evacuate the tagged stool you will need to clear untagged stool before the exam.

